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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------------|------------------|
| 10/758,917   | 01/16/2004  | Jack E. Lohman       | 190143.90091                | 7080             |
| 26710  | 7590        | 10/19/2005           |                             |                  |
| QUARLES & BRADY LLP<br>411 E. WISCONSIN AVENUE<br>SUITE 2040<br>MILWAUKEE, WI 53202-4497 |             |                      | EXAMINER<br>GEDEON, BRIAN T |                  |
|  |             |                      | ART UNIT                    | PAPER NUMBER     |
|  |             |                      | 3766                        |                  |

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/758,917 | <b>Applicant(s)</b><br>LOHMAN ET AL. |  |
|                              | <b>Examiner</b><br>Brian T. Gedeon   | <b>Art Unit</b><br>3766              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38-55 and 72-93 is/are allowed.
- 6) ☒ Claim(s) 1-15, 18, 20-30 and 93-100 is/are rejected.
- 7) ☒ Claim(s) 1, 16, 17, 19, 21, 31, 32, 35, 37, 38, 56-60, 63, 70 and 71 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/14/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 1 and 21 are objected to because of the following minor informalities: in both claim preambles, Examiner recommends changing "leas" to "least". Appropriate correction is required.
2. Claims 56-60, 63-68, 70, and 71 objected to because of the following informalities: due to the correction in numbering of claims 55-100 under 37 CFR 1.126, the above claims depend on the incorrect independent claim. The Examiner recommends changing the claims to reflect that they depend on claim 55 and not on claim 54. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-15, 18, and 20 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Baker et al. (US Patent no. 6,701,183).

In regards to claim 1, Baker et al. discloses a long term monitor for atrial fibrillation comprised of a housing 12 including right and left handles, 20 and 22,

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providing on their undersurfaces momentary contact electrodes 24, column 3 lines 40-42. The monitor includes a detector circuit to record ECG signals subsequent to the patient touching the first and second momentary contact electrodes 24, column 2 lines 25-28. The detector circuit communicates with the first and second momentary contact electrodes 24, and executes a stored program to receive ECG signals from a patient touching the first and second momentary electrodes 24, and detect a likelihood that the patient is experiencing an arrhythmia, atrial fibrillation in particular, and an output signal is provided to the patient if the likelihood is above a predetermined threshold, column 1 lines 66 – column 2 lines 1-6.

In regards to claim 2, a program stored in a microcontroller 36 executes a loop to detect connection of the patient's hands to the electrodes 24, column 4 lines 45-52.

In regards to claim 3, the program of the microcontroller executes a loop to detect the resistance between the electrodes 24 using circuitry to determine if the patient is making contact with the electrodes in order to activate the device, column 4 lines 45-52. Good electrical contact is made when the patient exerts the proper pressure to the electrodes 24, column 6 lines 10-14.

In regards to claim 4, upon placement of the patient's hands on the electrodes 24, the microcontroller 36 starts a timer, column 4 lines 53-54. The stop timer signal concludes the acquisition of ECG data, the time interval for the acquisition of ECG signals is normally a few minutes and substantially less than a day, which is typical with a cardiac evaluation monitor, column 5 lines 4-9.

In regards to claim 5, the electrodes 24 serve as operators for switches 25 to communicate with the microcontroller 36 in order to provide a signal that the device is being used, column 6 lines 3-7.

In regards to claim 6, the electrodes 24, each contact one of the patient's hands by means of a right handle 22 and a left handle 20.

In regards to claim 7, the electrodes 24 may be finger pads 19 sized to contact the patient for ECG readings, column 2 lines 12-15.

In regards to claim 8, the electrodes 24 may be spring loaded to recess into the housing 12 slightly when pressed and thus may serve as operators for switches 25 communicating with the microcontroller 36 to provide a signal indicating that the device is being used, column 6 lines 3-9.

In regards to claim 9, an indicator light 26 is positioned on the top surface of the housing 12. A green light shows when no irregularities are present and a red light indicates an arrhythmia, in particular atrial fibrillation, column 3 lines 51-56.

In regards to claim 10, the device includes recording media so that the atrial fibrillation detector circuit may record the received ECG signals subsequent to the patient touching the electrodes 24, column 2 lines 25-28.

In regards to claims 11 and 12, the monitor includes a communication circuit so that the atrial fibrillation detector may communicate the ECG signals to the communication circuit for transmission to a remote site, column 2 lines 35-39.

In regards to claim 13, a set of input/output lines are connected to a modem 44 which is connected to phone line connector cord 16 for communication of data over telephone lines, column 4 lines 15-19.

In regards to claim 14, an alarm clock routine 46 provides a second output signal to the patient to remind the patient to grasp the electrodes, column 2 lines 43-45.

In regards to claim 15, an LCD display 30 provides a graphic output including text messages instructing the patient in touching the first and second momentary contact electrodes and remaining in contact with the elements prior to generation of the output signal, column 2 lines 45-50.

In regards to claim 18, an indicator light 26 serves to provide an indication of the patient's heartbeat status, column 3 lines 51-56, and an audio transducer 42 serves as an indicator for reminding the patient to take a measurement of his or her heartbeat, column 4 lines 10-15.

In regards to claim 20, an alarm clock routine 46 performs alarm clock type functions well known in the art to provide a tone at a regular time to remind the patient to use the monitor, column 4 lines 33-37.

4. Claims 21-30 rejected under 35 U.S.C. 102(e) as being anticipated Baker et al. (US Patent no. 6,701,183).

In regards to claim 21, Baker et al. discloses a method for long term monitoring of atrial fibrillation comprised of right and left handles, 20 and 22, providing on their undersurfaces momentary contact electrodes 24, column 3 lines 40-42 for a patient to grasp. The monitor used to perform the method includes a detector circuit to record

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ECG signals subsequent to the patient touching the first and second momentary contact electrodes 24, column 2 lines 25-28. At no more than a predetermined interval, the ECG sample is collected from the patient when the patient makes contact with the momentary contact electrodes 24, wherein the data is collected for a short period of time substantially less than a daily interval, column 9 lines 1-5. The detector circuit communicates with the first and second momentary contact electrodes 24, and executes a stored program to receive ECG signals from a patient touching the first and second momentary electrodes 24, and detect a likelihood that the patient is experiencing an arrhythmia, atrial fibrillation in particular, and an output signal is provided to the patient if the likelihood is above a predetermined threshold, column 1 lines 66 – column 2 lines 1-6.

In regards to claim 22, please see argument for claim 2.

In regards to claim 23, please see argument for claim 3.

In regards to claim 24, the method is performed in the morning after the patient wakes, column 9 lines 14-15.

In regards to claim 25, please see parallel argument for claim 10.

In regards to claim 26, please see parallel argument for claim 11.

In regards to claim 27, please see parallel argument for claim 12.

In regards to claim 28, please see parallel argument for claim 13.

In regards to claim 29, please see parallel argument for claim 20.

In regards to claim 30, please see parallel argument for claim 15.

In regards to claim 36, atrial fibrillation monitor 10 is used to determine if atrial fibrillation is identified and should be transmitted to a physician, column 7 lines 15-18.

5. Claims 93-99 are rejected under 35 U.S.C. 102(e) as being anticipated by Baker et al. (US Patent no. 6,701,183).

In regards to claim 93, Baker et al. discloses a method for long term monitoring of atrial fibrillation comprised of right and left handles, 20 and 22, providing on their undersurfaces momentary contact electrodes 24, column 3 lines 40-42 for a patient to grasp. The monitor used to perform the method includes a detector circuit to record ECG signals subsequent to the patient touching the first and second momentary contact electrodes 24, column 2 lines 25-28. At no more than a predetermined interval, the ECG sample is collected from the patient when the patient makes contact with the momentary contact electrodes 24, wherein the data is collected for a short period of time substantially less than a daily interval, column 9 lines 1-5. The detector circuit communicates with the first and second momentary contact electrodes 24, and executes a stored program to receive ECG signals from a patient touching the first and second momentary electrodes 24, and detect a likelihood that the patient is experiencing an arrhythmia, atrial fibrillation in particular, and an output signal is provided to the patient if the likelihood is above a predetermined threshold, column 1 lines 66 – column 2 lines 1-6. A communication circuit may transmit ECG signals to a remote site, column 2 lines 35-39, and may provide a provision for a healthcare provider to review at a central computer 74, column 6 lines 43-45.

In regards to claim 94, please see parallel argument for claim 24.

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In regards to claim 95, please see parallel argument for claims 10 and 25.

In regards to claim 96, please see parallel argument for claims 16 and 26.

In regards to claim 97, please see parallel argument for claims 13 and 28.

In regards to claim 98, please see parallel argument for claims 20 and 29.

In regards to claim 99, please see parallel argument for claims 30 and 15.

6. Claim 100 is rejected under 35 U.S.C. 102(e) as being anticipated by Baker et al. (US Patent no. 6,701,183).

In regards to claim 100, Baker et al. discloses a method for long term monitoring of atrial fibrillation including a detector circuit to record ECG signals subsequent to the patient touching the first and second momentary contact electrodes 24, column 2 lines 25-28; for no more than a predetermined interval, the ECG sample is collected from the patient when the patient makes contact with the momentary contact electrodes 24, wherein the data is collected for a short period of time substantially less than a daily interval, column 9 lines 1-5. The detector circuit communicates with the first and second momentary contact electrodes 24, and executes a stored program to receive ECG signals from a patient touching the first and second momentary electrodes 24, and detect a likelihood that the patient is experiencing an arrhythmia, atrial fibrillation in particular, and an output signal is provided to the patient if the likelihood is above a predetermined threshold, column 1 lines 66 – column 2 lines 1-6. Decision block 92 analyzes the ECG data to see if atrial fibrillation has been detected, column 6 lines 66-67 – column 7 lines 1-2. If atrial fibrillation has been determined, the data is sent to a remote site for review by a qualified healthcare professional, column 7 lines 14-18.

***Allowable Subject Matter***

7. Claims 16, 17, 19, 31, 32, 34, 35 and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
8. Claims 38, 72 and 87 and all dependent claims are allowed.
9. Claim 55 and all of its dependent claims are allowed, however dependent claims 56-60, 63-68, 70 and 71 are objected to because of an informality regarding the independent claim they refer to, as stated in the "Claim Objections" section above.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1 and 6-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S.

Patent No. 6,701,183. Although the conflicting claims are not identical, they are not

patentably distinct from each other because both pertain to a long-term monitor using scheduled short-termed acquisition of data from the patient to determine if cardiac arrhythmia exists in the patient.

11. Claims 21 and 24-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-19 of U.S. Patent No. 6,701,183. Although the conflicting claims are not identical, they are not patentably distinct from each other because both pertain to a method of long-term monitoring of a patient for a cardiac arrhythmia comprised of using first and secondary contact electrodes sized to contact the patient.

### ***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Morganroth (US Patent no. 6,708,057) discloses a method and system of processing electrocardiographs that involve time stamping of the stored ECG data. Itoh (US Patent no. 6,587,712) discloses a portable electrocardiogram monitor that compares recorded data with stored data, and sounds an alarm when the data exceeds a predetermined rate. Hill et al. (US Patent no. 6,442,429) discloses a method and apparatus for diagnosis and treatment of arrhythmias. Vidrine et al. (US Patent no. 6,018,677) discloses a heart rate monitor using hand grips as transducers. McIntosh (US Patent no. 3,731,672) discloses a heart monitoring apparatus for a motor vehicle and senses ECG signals by means of hand grip electrodes placed on the steering wheel.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272 3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272 6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert E Pezzuto  
Supervisory Patent Examiner  
Art Unit 3766

BTG